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10/654,668

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Brian Rosenfeld

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12/07/2006

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EXAMINER

MORGAN, ROBERT W

ART UNIT

PAPER NUMBER

3626

DATE MAILED: 12/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/654,668 | Applicant(s) ROSENFELD ET AL. | |
| | Examiner Robert W. Morgan | Art Unit 3626 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/29/06.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>7/5/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice to Applicant

1. In the amendment filed on 8/29/06, the following has occurred: Claims 1-8 have been canceled and claims 9-39 have been added. Now claims 9-39 are presented for examination.

Information Disclosure Statement

2. The information disclosure statements filed 7/5/06 has been acknowledged and entered.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 9-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,772,585 to Lavin et al. in view of U.S. Patent No. 4,852,570 to Levine.

As per claim 9, Lavin et al. teaches a method for utilizing physician notes in a healthcare system comprising:

--the claimed inputting patient health data reflecting a current state of a patient and treatment objectives for the patient to an input device, wherein the patient health data is inputted via formatted input options presented by the input device and wherein the input device is connected to a network is met by the physician entering progress notes including subjective observation of the patient through actual examination and assessment notes listing conclusions based on the subjective and objective observation as well as a treatment plan are also presented at step 162 (see: column 9, lines 29-40). In addition, Lavin et al. teaches that each workstation

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(14, Fig. 1) can either being fixed or a portable computer such as the IBM ThinkPad capable of communicating with a network server (12, Fig. 1) (see: column 4, lines 43-55);

--the claimed receiving the patient health data in the healthcare system via the network is met by the workstation (14, Fig. 1) using graphic user interface data entry screens to receive new or existing patient information (see: column 7, lines 12-25). In addition, Lavin et al. teaches that each workstation (14, Fig. 1) can either being fixed or a portable computer such as the IBM ThinkPad capable of communicating with a network server (12, Fig. 1) (see: column 4, lines 43-55);

--the claimed accessing the patient health care data from a remote command center associated with the healthcare system via the network is met by the multiple clinic personnel and physician accessing various aspects of common database information regarding a specific patient or a group of patients (see: column 4, lines 8-10). In addition, Lavin et al. teaches that each workstation (14, Fig. 1) can either being fixed or a portable computer such as the IBM ThinkPad capable of communicating with a network server (12, Fig. 1) (see: column 4, lines 43-55); and

--the claimed accessing patient data elements of the patient stored in a database from the remote command center via the network is met by the multiple clinic personnel and physician accessing various aspects of common database information regarding a specific patient or a group of patients (see: column 4, lines 8-10). In addition, Lavin et al. teaches that each workstation (14, Fig. 1) can either being fixed or a portable computer such as the IBM ThinkPad capable of communicating with a network server (12, Fig. 1) (see: column 4, lines 43-55);

Lavin et al. fails to teach:

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--the claimed creating a rule for the patient using the patient health data and the patient data elements;

--the claimed applying a rules engine to selected patient data elements stored in the database to search for patterns of data and to produce an output indicative of a change in the medical condition of the patient; and

--the claimed utilizing the output from the rules engine to determine if intervention is warranted, wherein the monitoring and determining if intervention is warranted for the patient is directed from the remote command center.

Levine teaches microcard reader (11, Fig. 1) and keyboard selection terminal (12, Fig. 1) used to compare and detect any "trend" analysis from tests performed on the patient (see: column 5, lines 46-51). In addition, Levine teaches that the individual readings and test results can be variously mathematically processed to obtain differences, percentage changes, ratios, average readings, and others to assist in "trend" analysis of the medical condition of that individual (see: column 8, lines 17-23). This allows the physician to detect both long and short term changes in any measured condition of the individual (see: column 8, lines 26-28), suggesting that mathematical rules are created and applied to individual readings and test results to produce an output that is displayed to the physician to determine if intervention or help should be provided to the patient.

One of ordinary skill in the art the time the invention was made would have found it obvious to include creating and applying rules to patient data to produce an output report to the physician as taught by Levine with the system and method for managing patient medical records as taught by Lavin et al. with the motivation of providing a more detailed and informative

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manner of diagnosing the physiological health of an individual (see: Levine: column 2, lines 5-10).

As per claim 10, Lavin teaches the claimed inputting patient health data comprises inputting data on remote devices selected from the group consisting of wired devices and wireless devices. This limitation is met by the physician entering progress notes including subjective observation of the patient through actual examination and assessment notes listing conclusions based on the subjective and objective observation as well as a treatment plan are also presented at step 162 (see: column 9, lines 29-40). In addition, Lavin et al. teaches that each workstation (14, Fig. 1) can either being fixed or a portable computer such as the IBM ThinkPad capable of communicating with a network server (12, Fig. 1) (see: column 4, lines 43-55).

As per claim 11, Lavin teaches the claimed inputting patient health data comprises:

--the claimed selecting a note template is met by selecting and completing a diagnosis using the diagnosis screen (226, Fig. 17) (see: column 13, lines 29-30):

--the claimed selecting a structured data element associated with the selected template, wherein the selected structured data element is indicative of the current state of the patient and the treatment objectives for the patient, and incorporating the selected structured data element into the selected note template to create a completed template is met by selecting and completing a diagnosis using the diagnosis screen (226, Fig. 17) (see: column 13, lines 29-30). In addition, Lavin et al. teaches at the completion of the progress note task, the physician saves the notes and the processor (22, Fig. 2) will direct the entered information into the appropriate data tables in memory (20, Fig. 2) (see: column 11, lines 57-60);

--the claimed associating the completed template with the patient is met by the table information which is stored by patient identification number, date and physician (see: column 11, lines 60-66); and

--the claimed releasing the completed template to the healthcare system is met by the common graphic user interface used by system (10, Fig. 1) that allows authorized user to manage medical information and provides physician with useful diagnosis tools (instructions) to assist in examination and diagnosis of the patient (see: column 16, lines 6-10).

As per claim 12, Lavin teaches the claimed receiving the patient health data in the healthcare system comprises:

--the claimed time stamping the patient health data when it is released to the healthcare system is met by selecting and completing a diagnosis using the diagnosis screen (226, Fig. 17) (see: column 13, lines 29-30) In addition, Lavin et al. teaches at the completion of the progress note task, the physician saves the notes and the processor (22, Fig. 2) will direct the entered information into the appropriate data tables in memory (20, Fig. 2) (see: column 11, lines 57-60). Furthermore, Lavin et al. teaches that the progress notes screen (200, Fig. 2) that receives and stores subjective and objective data by date and time, entered by the physician (see: column 12, lines 8-25; and

--the claimed storing the time stamped patient health data in a datastore accessible to remote command center is met by the progress notes screen (200, Fig. 2) that receives and stores subjective and objective data by date and time, entered by the physician (see: column 12, lines 8-25). In addition, Lavin teaches multiple clinic personnel and physician accessing various aspects of common database information regarding a specific patient or a group of patients using a fixed

or a portable computer such as the IBM ThinkPad capable of communicating with a network server (12, Fig. 1) (see: column 4, lines 8-55).

As per claim 13, Levine teaches the claimed patient rule comprises an algorithm. This feature is met by the individual readings and test results which are mathematically processed to obtain differences, percentage changes, ratios, average readings, and others to assist in “trend” analysis of the medical condition of that individual (see: column 8, lines 17-23).

As per claims 14-19, Lavin and Levine teach a patient selection screen (170, Fig. 5) where the user enters patient information such name, insurance company name, primary physician, and notes on items such as patient scheduling (see: Lavin: column 6, lines 45-57). In addition, Lavin and Levine teach many different physiological test results are record such as blood pressure (25, Fig. 1), heartbeat (26, Fig. 1) and other medical information including any medication in use (38, Fig. 1) and surgery performed (39, Fig. 1) since last recorded test (see: Levine: column 4, lines 1-39).

Lavin and Levine fail to explicitly teach the selected patient data elements comprise a physiological data element of the patient and a laboratory data element of the patient, another physiological data element of the patient and at least two data elements of the patient selected from the group consisting of a physiological data element, a clinical data element of the patient, a medication data element of the patient, and a laboratory data element of the patient.

However these differences are only found in the non-functional data used in the method for utilizing physician notes in a healthcare system. The patient data elements comprise a physiological data element of the patient and a laboratory data element of the patient, another physiological data element of the patient and at least two data elements of the patient selected

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from the group consisting of a physiological data element, a clinical data element of the patient, a medication data element of the patient, and a laboratory data element of the patient are not functionally related to the method for utilizing physician notes in a healthcare system. Thus, this description material will not distinguish the claimed invention from the prior art in terms of patentability, *see Cf. In re Gulack*, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983); *In re Lowry*, 32 F.3d 1579, 32 USPQ2d 1031 (Fed. Cir. 1994).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include selecting different patient data element because such data does not functionally relate to the method for utilizing physician notes in a healthcare system and merely selecting different types of patient data elements from that in the prior art would have been obvious matter of design choice. *See In re Kuhle*, 526 F.2d 553, 555, 188 USPQ 7, 9 (CCPA 1975).

As per claims 20-21, Lavin teaches that a physician entering progress notes including subjective observation of the patient through actual examination and assessment notes listing conclusions based on the subjective and objective observation as well as a treatment plan are also presented at step 162 (see: column 9, lines 29-40). The Examiner considers the treatment plan as information used to determine whether to issue a patient intervention (treatment plant) protocol and order.

Lavin fails to teach utilizing the output from the rules engine to determine if intervention is warranted.

Levine teaches microcard reader (11, Fig. 1) and keyboard selection terminal (12, Fig. 1) used to compare and detect any "trend" analysis from tests performed on the patient (see: column

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5, lines 46-51). In addition, Levine teaches that the individual readings and test results can be variously mathematically processed to obtain differences, percentage changes, ratios, average readings, and others to assist in “trend” analysis of the medical condition of that individual (see: column 8, lines 17-23). This allows the physician to detect both long and short term changes in any measured condition of the individual (see: column 8, lines 26-28), suggesting that mathematical rules are created and applied to individual readings and test results to produce an output that is displayed to the physician to determine if intervention or help should be provided to the patient.

The obviousness of combining the teaching of Levine within the teaching of Lavin are discussed in rejection of claim 9 and incorporated herein.

As per claim 22, it is rejected for the same reasons as set forth in claim 14.

As per claim 23, Levine teaches the claimed output indicative of the change in the medical condition of the patient comprises an output indicative of improvement of the condition of the patient. This limitation is met by the microcard reader (11, Fig. 1) and keyboard selection terminal (12, Fig. 1) used to compare and detect any “trend” analysis from tests performed on the patient (see: column 5, lines 46-51). In addition, Levine teaches that the individual readings and test results can be variously mathematically processed to obtain differences, percentage changes, ratios, average readings, and others to assist in “trend” analysis of the medical condition of that individual (see: column 8, lines 17-23). This allows the physician to detect both long and short term changes in any measured condition of the individual (see: column 8, lines 26-28).

As per claim 24, The method for utilizing physician notes in a healthcare system of claim 9, wherein the output indicative of the change in the medical condition of the patient comprise

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data indicative of degradation of the condition of the patient. This limitation is met by the microcard reader (11, Fig. 1) and keyboard selection terminal (12, Fig. 1) used to compare and detect any “trend” analysis from tests performed on the patient (see: column 5, lines 46-51). In addition, Levine teaches that the individual readings and test results can be variously mathematically processed to obtain differences, percentage changes, ratios, average readings, and others to assist in “trend” analysis of the medical condition of that individual (see: column 8, lines 17-23). This allows the physician to detect both long and short term changes in any measured condition of the individual (see: column 8, lines 26-28).

As per claim 25, Lavin teaches a system for utilizing physician notes in a healthcare system comprising:

- the claimed network is met by the network server (12, Fig. 1);

- the claimed remote command center connected to the network, wherein the remote command center comprises a database is met by each workstation (14, Fig. 1) having memory (20, Fig. 1) connecting to the network server (12, Fig. 1) (see: column 4, lines 40-42);

- an input device connected to the network, wherein the input device is adapted for:

- the claimed presenting formatted input options is met by the physician selecting from a main menu screen (28, Fig. 2) to access the clinical examination module (see: column 8, lines 59-67); and

- the claimed receiving patient health data reflecting a current state of a patient and treatment objectives for the patient in accordance with the formatted input options is met by the physician entering progress notes including subjective observation of the patient through actual examination and assessment notes listing conclusions based on the subjective and objective

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observation as well as a treatment plan are also presented at step 162 (see: column 9, lines 29-40). In addition, Lavin teaches that the physician selects from a main menu screen (28, Fig. 2) in order to access the clinical examination module (see: column 8, lines 59-67).

Lavin teaches that each workstation (14, Fig. 1) having memory (20, Fig. 1) connects to the network server (12, Fig. 1) (see: column 4, lines 40-42). In addition, Lavin teaches that the physician selects from a main menu screen (28, Fig. 2) in order to access the clinical examination module (see: column 8, lines 59-67).

Lavin fails to teach:

- the claimed creating a rule for the patient using the patient health data and the patient data elements;

- the claimed applying a rules engine to selected patient data elements stored in the database to search for patterns of data and to produce an output indicative of a change in the medical condition of the patient; and

- the claimed utilizing the output from the rules engine to determine if intervention is warranted.

Levine teaches microcard reader (11, Fig. 1) and keyboard selection terminal (12, Fig. 1) used to compare and detect any "trend" analysis from tests performed on the patient (see: column 5, lines 46-51). In addition, Levine teaches that the individual readings and test results can be variously mathematically processed to obtain differences, percentage changes, ratios, average readings, and others to assist in "trend" analysis of the medical condition of that individual (see: column 8, lines 17-23). This allows the physician to detect both long and short term changes in any measured condition of the individual (see: column 8, lines 26-28), suggesting that

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mathematical rules are created and applied to individual readings and test results to produce an output that is displayed to the physician to determine if intervention or help should be provided to the patient.

The obviousness of combining the teaching of Levine within the teaching of Lavin are discussed in rejection of claim 9 and incorporated herein.

As per claims 26-39, they are rejected for the same reasons set forth in claims 10-19 and 23-24.

Response to Arguments

5. Applicant's arguments with respect to claims 9-39 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

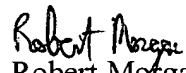
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert W. Morgan whose telephone number is (571) 272-6773.

The examiner can normally be reached on 8:30 a.m. - 5:00 p.m. Mon - Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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Art Unit 3626


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